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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/258,600	02/26/1999	Dana M. Fowlkes	CPI-012CP4DV	4086

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EXAMINER
LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
2636	

DATE MAILED: 02/12/2003

Please find below and or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/258,600	FOWLKES ET AL
Examiner	**Art Unit**
David A Lambertson	1636

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002*

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43,46,48-52,54-66,69-93,96 and 97* is/are rejected.

7)☒ Claim(s) *44,45,47,53,67,68,94,95,98 and 99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☒ Other: *Notice to Comply*

DETAILED ACTION

Priority

Applicant's claim for domestic priority to US Application serial numbers 08 461598 (now US Patent No. 5,876,951), 08 322137 (now US Patent No. 6,100,042), 08 309313 (now abandoned), 08 190328 (now abandoned) and 08 041431 (now abandoned) under 35 U.S.C. 120 is acknowledged and granted.

Drawings

New corrected drawings are required in this application because of the reasons set forth in the Draftsperson's comments in attached form PTO-948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the specification contains multiple peptide sequences of greater than 4 amino acids in length, requiring that they be identified by SEQ ID NOS. These sequences are located at line 29 of page 55, line 20 of page 56, lines 1 and 4 of page 58, line 17 of page 59, lines 4-23 of page 94, line 23 of page 112, lines 24, 35 and 36 of page 123, lines 25 and 26 of page 124, lines 2-13 of page 125, lines 3 and 4 of page 126, Table 5 on pages 150-151 and Table 7 on page 154. However, it appears that these sequences are excerpts from those sequences that have already been disclosed with SEQ ID

NOS, therefore it may not be necessary to provide new sequence identifiers and a new sequence listing (paper copy and CRF). If the sequences are indeed smaller portions of an already identified sequence, they must be identified in the specification by indicating what portions of those sequences are represented (e.g., SEQ ID NO: X, amino acids Y to Z). If the sequences are not portions of an already disclosed sequence, applicant is required to comply with the requirements of 37 CFR 1.821 through 1.825, and provide a new paper copy and CRF of the sequence listing containing the newly identified sequences, a statement indicating that both the paper copy and CRF are the same, and a statement indicating that no new matter has been introduced into the specification. In addition, applicant is required to amend the specification to properly indicate the sequences with their corresponding SEQ ID NOS. If the sequence listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP 2422.05.

Although the instant application is not in sequence compliance as indicated above, the non-compliance does not preclude the examination of the claims on the merits.

Claim Objections

Claim 59 is objected to because of the following informalities: the claim recites the terminology "an IGP dehydratase gene" without first identifying what the abbreviation IGP represents. Indicating either the full length name of the enzyme, or its genetic name (*HIS3*) is required. The latter is preferable to endow uniformity to claims 59, 73, 81 and 90. In claim 73,

HIS3 should be italicized. Additionally, it is noted that the yeast genes (and proteins; for example with respect to Ste3 in claim 97) all have a space between the letters and the numbers, and that this does not conform to proper nomenclature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "endogenous pheromone system protein" lacks antecedent basis and is indefinite because it is unclear if the claim is referring to any pheromone system protein, or a specific pheromone system protein (e.g., the endogenous protein corresponding to the first heterologous gene).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined

was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 43, 48, 54, 57, 58, 60, 61, 63-65, 96 and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by King *et al.* (US Patent No. 5,482,835; henceforth King; see entire document).

It is noted that although King has a filing date of June 3, 1993, the priority date is September 13, 1990.

King teaches a yeast cell having a pheromone system, where the yeast cell co-expresses a first heterologous gene encoding a surrogate of a yeast pheromone receptor (βAR) and a second heterologous gene encoding a peptide (Gαs) that modulates the interaction of the receptor with the pheromone system (see for example the Abstract, and column 8 line 55 to column 9, line 7). The yeast cell can either be desensitized to the pheromone signaling cascade upon the deletion of the endogenous Gα subunit, encoded by the *GPA1* gene (see for example column 9, lines 10-35), or it can be wild type with respect to the pheromone signaling cascade (see for example column 8 line 55 to column 9, line 7). When the cell is a wild type cell of the *Saccharomyces* genera (see for example column 4, lines 34-40), it can either be responsive to α-factor (express Ste2p), or it can be responsive to **a**-factor and express Ste3p. The host cell can also be engineered to comprise a selectable marker (lacZ) operably linked to a pheromone responsive activated promoter element, specifically the *FUS1* promoter (see column 9, lines 44-57). A number of polypeptides can be assayed for modulating this surrogate pheromone system (see for example column 10, lines 3-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over King as applied above in view of Reneke *et al.* (*Cell* **55**: 226-234, 1988; see entire document; henceforth Reneke).

The teachings of King are applied here as set forth above in the rejection under 102(e).

King does not teach the further disruption of *SST2* to prevent desensitization of the host cell to the activation of the pheromone signaling pathway.

Reneke teaches that *SST2* is involved in the desensitization of a yeast host cell to activation of the pheromone response pathway, and that inactivation of the *SST2* gene results in an increased sensitivity of the yeast host cell to the pheromone response pathway (see for example page 226, the second full paragraph), which results in a greater ability to detect activation of a pheromone response.

It would have been obvious to the ordinary skilled artisan to combine the teachings of King and Reneke because both references involve the activation of the pheromone signaling pathway in yeast, hence the teachings are related to the same technical field. The ordinary skilled artisan would have been motivated to combine the teachings in order to accentuate the

level of detection of the pheromone response in King because the inactivation of *SST2* clearly would enhance the response to pheromone receptor activation, as taught by Reneke.

Absent evidence to the contrary and given the teachings of the stated prior art and the high level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over King as applied above in view of Chang *et al.* (*Cell* **63**: 999-1011, 1990; see entire document; henceforth Chang).

The teachings of King are applied here as set forth above in the rejection under 102(e).

King does not teach the further disruption of *FAR1* to prevent cell growth arrest in the host cell following activation of the pheromone signaling pathway.

Chang teaches that the *FAR1* gene product is necessary for the cell cycle arrest of yeast cells that are responding to activation of the pheromone pathway, and that mutating the *FAR1* gene results in the activation of the pheromone signaling pathway in the absence of cell cycle arrest (see for example the Abstract).

It would have been obvious to the ordinary skilled artisan to combine the teachings of King and Chang because both references involve the activation of the pheromone signaling pathway in yeast, hence the teachings are related to the same technical field. The ordinary skilled artisan would have been motivated to combine the teachings in order to prevent the host cells of King from experiencing a growth arrest in response to the activation of the surrogate

pheromone signaling pathway, therefore avoiding a potential impediment to the detection assay comprising cell growth arrest and a corresponding drop in signal detection, as taught by Chang.

Absent evidence to the contrary and given the teachings of the stated prior art and the high level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over King as applied above in view of Sikorski et al. (*Genetics* **122**: 19-27, 1989; see entire document; henceforth Sikorski).

The teachings of King are applied here as set forth above in the rejection under 102(e).

King does not teach the use of *HIS3* as a selectable marker for the indication of transcriptional activation, in this case by the pheromone signaling cascade.

Sikorski teaches the use of the *HIS3* gene as a selectable marker in strains containing auxotrophic mutations of the *HIS3* gene as a means for screening yeast cells. This allows a nutritional selection without the need for an additional assay to determine the presence of the *HIS3* gene (see for example page 19, right-hand column, first full paragraph).

It would have been obvious to the ordinary skilled artisan to combine the teachings of King and Sikorski because both references correspond to the selection of a particular yeast that expresses a genetic marker, although the genetic markers are different (King uses lacZ, whereas Sikorski uses *HIS3*). The ordinary skilled artisan would have been motivated to combine the teachings because the method of Sikorski involves a nutritional selection and does not require an

enzymatic assay, such as the β-galactosidase assay required for monitoring the presence of lacZ in King, therefore the selection process would be simpler and more rapid.

Absent evidence to the contrary and given the teachings of the stated prior art and the high level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43, 46, 48-52, 54-66 and 69-93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-18, 24, 29, 35, 36, 38, 39 and 41 of U.S. Patent No. 6,100,042 (henceforth the '042 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons given below.

Claims 1-4, 6-19, 24, 29, 35, 36, 38, 39 and 41 of the '042 patent are directed towards yeast cells expressing a heterologous gene encoding for a G-protein coupled receptor (GPCR)

with signal transduction activity and a second heterologous gene (which can originate from a polypeptide expressing library) encoding an effector of the signaling activity of the GPCR, whereby the modulation of the activity of the GPCR by the second heterologous gene can be monitored by a detectable signal (claim 1). Although the claims do not specifically indicate that the peptide library include at least 10^7 different peptide sequences, a preferred embodiment of the invention is to use a library expressing at least 10^7 different peptide sequences. The GPCR can be a surrogate for an endogenous yeast pheromone receptor (claim 2) where the yeast strain is compromised in the endogenous pheromone pathway by mutation, making the endogenous receptor non-functional or not expressed (claims 3, 4 and 6). Additional methods of disrupting the pheromone pathway are by attenuating the functional expression of the *FAR1* and *SST2* genes (claims 7 and 8). In particular embodiments of the invention, a heterologous and or chimeric G-proteins, particularly the Gα subunit, is used to facilitate or allow interaction between the heterologous GPCR and the downstream signaling pathway (claims 9-11). The detectable signal can be activated by the pheromone signal by operably linking the marker (e.g., *HIS3*) to a pheromone pathway responsive promoter, in particular the *FUS1* promoter (claims 12-15). In order to facilitate the secretion of the polypeptide encoded by the heterologous second gene into the periplasmic space to test its ability to affect the GPCR, the polypeptide can be fused to the leader peptide of yeast **a**-factor (or α-factor, depending on the yeast cell type), especially in instances where the yeast is of the species *Saccharomyces cerevisiae* (claims 16-18). The invention also claims a method of using the yeast cells to identify a modulator of the GPCR in a mixture of said yeast cells that expresses a library of polypeptides, where the yeast cell is *Saccharomyces cerevisiae* (claim 41), and can have inactivating mutations in the endogenous

pheromone pathway (claims 24 and 29) and a selectable marker (e.g., *HIS3*, β-galactosidase, etc.) operably linked to a pheromone responsive pathway promoter (e.g., *FUS1*) (claims 35, 36, 38 and 39).

The instant claims are drawn to yeast cells expressing a heterologous pheromone receptor with signal transduction activity and a second heterologous gene (which can originate from a polypeptide expressing library) encoding an effector of the signaling activity of the pheromone receptor, whereby the modulation of the activity of the pheromone receptor can be monitored by a detectable signal. The limitations for the instant claims include those limitations that are set forth above for the claims of the '042 patent.

The instant claims differ from the claims of the '042 patent in that they are genus claims that are anticipated by the specific embodiments claimed in the '042 patent. Specifically, the GPCR of the '042 claims can be a member of the surrogate yeast pheromone receptor as claimed in the instant claims.

The instant claims are obvious in light of the '042 claims because the instant claims are directed to the expression of any heterologous gene of a pheromone receptor gene, and a GPCR can be a pheromone receptor gene, therefore the specific embodiment anticipates the generic embodiment. The additional limitations are all applied to the specific embodiment, and are therefore equally applicable to the broad invention of which the species is a member. Absent evidence to the contrary, the ordinary skilled artisan would have had more than a reasonable expectation of success when practicing the invention claimed in the instant application because the instant invention is a broad genus that is anticipated by the specific embodiment of the '042 claims.

Allowable Subject Matter

Claims 44, 45, 47, 53, 67, 68, 94, 95, 98 and 99 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
February 7, 2003

PATENT EXAMINER
Gerald G. Lambertson JR
A.U. 1636

Notice to Comply

Application No.	Applicant(s)
09/258600	Fowlkes *et al.*
Examiner	**Art Unit**
David A. Lambertson	1636

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990) and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing".

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequences in application not in Sequence Compliance (see attached Office Action).

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.